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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/828,323 03/28/97 O'DONNELL

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EXAMINER

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ART UNIT

PAPER NUMBER

1652

25

DATE MAILED: 02/08/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**08/828,323**

Applicant(s)  
**Michael O'Donnell**

Examiner  
**Richard Hutson**

Group Art Unit  
**1652**



☒ Responsive to communication(s) filed on Nov 20, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 5-8, 10, 12-17, 19, 20, 54, 55, 57-60, 62, 64, and 65 is/are pending in the applicat

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 5, 7, 12-17, 19, 20, 54, 55, 59, 60, 64, and 65 is/are rejected.

☒ Claim(s) 6, 8, 10, 57, 58, and 62 is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### DETAILED ACTION

1. The art unit location of your application and examiner has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit **1652**, Examiner **Richard Hutson Ph.D.**

#### *Continued Prosecution Application*

2. The request filed on 9/20/2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/828,323 is acceptable and a CPA has been established. An action on the CPA follows.

3. Applicants amendment of claims 5, 14, 20, 54 and 59 is acknowledged. Claims 5-8, 10, 12-17, 19, 20, 54, 55, 57-60, 62, 64 and 65 are at issue and are present for examination.

Applicants' arguments filed on 11/20/2000, paper No. 24, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

#### *Claim Objections*

4. Claims 6, 8, 19, 57, 58, 62, 64 and 65 are objected to because of the following informalities:

Claim 19 recites "...corresponding to amino acids residues 1-158..." This should read "...corresponding to amino acid residues 1-158..."

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Claims 6, 8, 10, 15, 57, 58 and 62 depend from rejected claims. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 17, 55 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 55 are indefinite in that it is confusing in the recitation "...wherein the protein corresponds to an amino acid sequence corresponding to SEQ ID NO: 10 (claim 17) or SEQ ID NO: 9 (claim 55)" in that the word "corresponds" is used multiple times to describe the same protein. It is suggested that a simpler clearer way of reciting the same limitation might be something like "...wherein the protein has the amino acid sequence of SEQ ID NO: 10 (claim 17) or SEQ ID NO: 9 (claim 55)"

Claim 60 is indefinite in that it is confusing in the recitation "...wherein the DNA molecule corresponds to an nucleotide sequence corresponding to SEQ ID NO: 6" in that the word "corresponds" is used multiple times to describe the same DNA molecule. It is suggested that a simpler, clearer way of reciting the same limitation might be something like "...wherein the DNA molecule has the nucleotide sequence of SEQ ID NO: 6."

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7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 5, 7, 12, 13, 14, 16, 19, 20, 54, 59, 64 and 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 5, 7, 12 and 13, 14, 16 are drawn to an isolated DNA molecule encoding, and the protein corresponding to the  $\delta'$  subunit of polymerase III holoenzyme wherein the DNA molecule comprises a nucleic acid structure which hybridizes to a nucleotide sequence corresponding to SEQ ID NO: 11 or SEQ ID NO: 12 or SEQ ID NO: 13 when hybridization is performed in 2 X SSC, 0.2% SDS at 42°C and a host cell comprising said DNA (claims 5, 13 14), wherein the subunit has a molecular weight of 36.9 kDa. (claims 7 and 16). Claim 19 is drawn to an isolated protein subunit of polymerase III holoenzyme, wherein the subunit has an amino acid sequence corresponding to amino acids residues 1-158 of SEQ ID NO: 10 and claim 20 is drawn to an isolated protein subunit of polymerase III holoenzyme, wherein the subunit has an amino acid sequence corresponding to amino acid residues 107-158 of SEQ ID NO: 10. Claims 54, 59, 64 and 65 are drawn to an isolated DNA molecule encoding (claim 59), and the protein corresponding to the  $\delta$  subunit of polymerase III holoenzyme (claim 54) wherein the DNA molecule comprises a nucleic acid structure which hybridizes to a nucleotide sequence

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corresponding to SEQ ID NO: 6 when hybridization is performed in 2 X SSC, 0.2% SDS at 42°C and a expression system and host cell comprising said DNA (claims 64 and 65). The specification, however, only provides the representative species of  $\delta$  and  $\delta'$  subunits of polymerase III holoenzyme, DNA encoding said subunits and host cells comprising said DNAs represented by proteins having the amino acid sequence corresponding to SEQ ID NOs: 9 and 10.

There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these proteins, DNAs and host cells by any identifying structural characteristics or properties other than the characteristics recited in claims, for which no predictability of function is apparent.

The genus of proteins, DNAs and host cells that are claimed is a large variable genus with potentiality of comprising or encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus (i.e the sequence encoding SEQ ID NO: 2) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

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9. Claims 5, 7, 12, 13, 14, 16, 19, 20, 54, 59, 64 and 65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated naturally occurring DNA molecule encoding, and the protein corresponding to the  $\delta'$  or  $\delta$  subunit of polymerase III holoenzyme wherein the DNA molecule comprises a nucleic acid structure which hybridizes to a nucleotide sequence corresponding to SEQ ID NO: 11 or SEQ ID NO: 12 or SEQ ID NO: 13 ( $\delta'$  subunit) or SEQ ID NO: 6 ( $\delta$  subunit) when hybridization is performed in 2 X SSC, 0.2% SDS at 42°C and a host cell comprising said DNAs or an isolated naturally occurring subunit of polymerase III holoenzyme, wherein the subunit has an amino acid sequence corresponding to amino acids residues 1-158 of SEQ ID NO: 10 or residues 107-158 of SEQ ID NO: 10., does not reasonably provide enablement for any isolated DNA molecule encoding, and protein corresponding to the  $\delta'$  or  $\delta$  subunit of polymerase III holoenzyme wherein the DNA molecule comprises a nucleic acid structure which hybridizes to a nucleotide sequence corresponding to SEQ ID NO: 11 or SEQ ID NO: 12 or SEQ ID NO: 13 when hybridization is performed in 2 X SSC, 0.2% SDS at 42°C and a host cell comprising said DNA or an isolated subunit of the polymerase III holoenzyme, wherein the subunit has an amino acid sequence corresponding to amino acids residues 1-158 of SEQ ID NO: 10 or residues 107-158 of SEQ ID NO: 10.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of variant subunits and DNAs encoding

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said variants broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the  $\delta$  and  $\delta'$  subunits of polymerase III holoenzyme, DNA encoding said subunits and host cells comprising said DNAs represented by the proteins having the amino acid sequence corresponding to SEQ ID NOs: 9 and 10.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any  $\delta$  and  $\delta'$  subunits of polymerase III holoenzyme, DNA encoding said subunits because the specification does not establish: (A) regions of the proteins structure which may be modified without effecting polymerase activity; (B) the general tolerance



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of  $\delta$  and  $\delta'$  subunits of polymerase III holoenzyme to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of the  $\delta$  and  $\delta'$  subunits of polymerase III holoenzyme with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid modifications of any  $\delta$  and  $\delta'$  subunits of polymerase III holoenzyme or DNA encoding said subunits. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of ? having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on M-F from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapy Achutamurthy (Murthy), can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014.

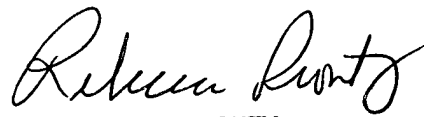
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard Hutson Ph.D.  
2/5/2001

  
**REBECCA E. PROUTY**  
**PRIMARY EXAMINER**  
**GROUP 1800**  
1652